DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

D1078B

January 8, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

VIA TELECOPIER and

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-24

Daniel L. Bissonnette
President
Centre Manufacturing Inc.
857 Payne Avenue
St. Paul, Minnesota 55101

Dear Mr. Bissonnette:

A review of labels for suntanning products distributed by your firm has revealed violations of the Food Drug and Cosmetic Act [the Act].

Three (3) of your own-label suntanning products and other suntanning products manufactured by your firm for private label distributors are covered by this letter. [See listing below]

product labels list "tyrosine" as an ingredient. The labeling for these products also includes terms such as:

"...a fast acting intensifying accelerator containing Unipertan 24 (tyrosine, riboflavin & collagen)...";

"...a fast acting natural tan intensifying accelerator...";

"...speeds up the natural tanning process by working with nature's own tanning element, melanin, to give you a richer, deeper tan";

"...with Unipertan 24 speeds up the natural tanning process by working with nature's own tanning element, melanin...";

"...a multipurpose tanning accelerator...";

"Melanin Accelerator Plus";

"Ultimate Accelerator";

"Amplifier Lotion with Tyrosine";

"Amplifier Lotion with Unipertan 24";

"Indoor/Outdoor";

"...allows you to spend less time in the sun..."; and

"...speeds up the tanning process...."

The Tentative Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use published in the May 12, 1993, Federal Register, states that any product purporting to "accelerate the tanning process" or "stimulate the production of melanin" is claiming to affect the structure and function of the body and is, therefore, a drug within the meaning of Section 201(g) of the Act. We are not aware of any data demonstrating that tyrosine or its derivatives are effective in stimulating the production of melanin. We are also unaware of any drug with the composition of these articles marketed in the United States on or before December 4, 1975, for the uses intended for your products, nor are we aware that drugs of these compositions are generally recognized as safe and effective for these labeled uses. Thus, any product containing tyrosine or its derivative and claiming to accelerate the tanning process is an unapproved new drug within the meaning of Section 201(p) of the Act, and may not be legally marketed in the United States without an approved New Drug Application (Section 505 of the Act). These products are also misbranded in that the labeling fails to bear adequate directions for use for the conditions that are offered (Section 502(f)(1) of the Act).

List of product labels discussed above:

Own Label products:

"Island Glow™ Maui Magic™"
"Island Glow™ Native Tan™"
"Island Glow™ Bronzing Gel™"

Private Label products:

The products listed below are further misbranded within the meaning of Section 502(a) of the Act and Title 21 Code of Federal Regulations (CFR) §201.1 as follows:

- lack the name of the manufacturer or distributor [21 CFR Part 201.1(a)].
- lack qualifying phrases for the distributor [21 CFR §201.1h(5)].
- and " are missing the complete address that includes the ZIP code and/or the state name [21 CFR §201.1(i)].

At the conclusion of our most recent inspection of your drug manufacturing facility located in St. Paul, Minnesota you were issued a Notice of Inspectional Observations, form FDA-483. We acknowledge receipt of your response to the items cited on this form. A copy of the FDA-483 is attached to this letter and we request your response to this letter include an update of the corrective actions you have taken to correct the deviations cited on this form.

The violations cited in this letter are not necessarily intended to constitute an all-inclusive statement of all the violations that may exist for products marketed by your firm. You should review the conditions of all of your firm's products to ensure that they are in compliance with the requirements of the Act. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when

considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days please state the reason for the delay and the time within which corrections will be implemented.

Your reply should be sent to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely yours,

John Feldman
Director
Minneapolis District

LRM/ccl